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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,414	05/30/2001	Anton-Lewis Usala	35626/234825	7087

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EXAMINER	
GUPTA, ANISH	
ART UNIT	**PAPER NUMBER**
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,414	USALA, ANTON-LEWIS	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,31-42,46-48 and 50-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,31-42,46-48 and 50-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants amendment, filed 11-25-08, is acknowledged. Claim 1, 32, and 48 were amended. Claims 56-60 were added. Claims 1-28, 30-44, 46-48, 50-60 are pending in this application.

Claim Rejections - 35 USC § 103

2. The rejection of claims 1-55, rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (WO00/02999) in view of Miller et al. and Mansbridge et al. in further view of Davis or Pickart et al. is hereby withdrawn in light of the 1.131 declaration submitted by Applicants.

3. The rejection of claims 1-55, rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (US 6231881) in view of Miller et al. and Mansbridge et al. in further view of Davis or Pickart et al. is hereby withdrawn in light of the statement made by the reference '881was owned by, or subject to an obligation of assignment as to the same entities as the present application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-29, 31-42, 46-48, and 50-60 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6,261,587 in view of Miller and in further view of Davis or Pickart et al.

The US patent claims a method of stimulating visualization at a site in a mammal by contacting the site with a matrix comprising denatured gelatin, dextran, nitric oxide inhibitor and a polar amino acid selected from Arginine, lysine, or glutamic acid (see claim 38). The gelatin is in the form of denatured collagen and is in the concentration range of between .01 to about 40mM of denatured collagen (see claim 44). Note that this concentration range is the same ranged claimed in claim 2 of the instant application. Further, the concentration of dextran is between 0 to about 2mM (claim 45) and polar amino acid between 3 to about 150 mM (claim 42). Both of the claimed concentration range is with the range claimed in claims 5, 8-9, and 33-36 of the instant application for dextran and the polar amino acids. Moreover, there is also the same concentration ranged claimed for the specific amino acids of glutamic, lysine and Arginine (see claim 43 of the US patent and claim 11-15 of the instant application. The nitric oxide inhibitors claimed in the US patent include dextran, heparin, cysteine, L-arginine, and aminoguanidine (see claims 21, 39-41 of the US patent). These nitric oxide inhibitors, including the concentration claimed in the US Patent, are similar to those claimed in claims 17-24 and 37-44 of the instant application. Note that claim 47 of the US patent claims a composition comprising dextran, denatured collagen, aminoguanidine, glutamic acid, lysine and arginine. This composition is similar to the composition claimed in claim 48 of the instant application. The difference between the US Patent and the claimed invention is that the US Patent does not teach the treatment of diabetic foot ulcers.

However, Miller teach that therapy for the treatment of diabetic foot ulcers includes vascular repair of the ulcers (see abstract). Miller et al. states that an ulcer gores through granulation and

reepithelialization (see page 761). Further, the reference suggest that numerous agents can be administered to the to the ulcer site to provide an optimal environment for healing. These include antibiotics and growth factors that result in the stimulation of granulation of tissue (see page 762, paragraph bridging column 1 an d2). It is well known in the art that granulation of tissue consists of new blood vessel formation, fibroblast activity, and re-epitelialization (see col., lines 29-35 of Davis US 5487899 and Col. 1, lines 28-35 of Pickart et al. US 5059588). Mansbridge also teaches that the angiogenesis (i.e. vascularization) is a goal for treating diabetic foot ulcers. This reference disclose that a goal of treatment for chronic diabetic foot ulcers is to redirect to an acute course and to reinstate normal wound healing. "This requires angiogenesis to improve the blood supply, and provision of suitable substratum for re-reepithelialization." (see page 404). The reference specifically discloses the mechanism of healing diabetic foot ulcers involves multiple components acting in concert, which include angiogenesis and promotion of re-reepithelialization (see page 413). The reference specifically demonstrates the beneficial effects of an angiogenic agent in the treatment of diabetic foot ulcers. The reference specifically points to angiogenesis as one of the mechanism by which this agent exerts the benefit (see page 412-413) Thus, since the US patent teaches method of treating disorders revascularization and since the art recognizes that revascularatization, a component of angiogenesis, is important in the healing diabetic foot ulcers, it would have been obvious to use the claimed composition for the treatment of foot ulcers because therapy for diabetic foot ulcers include vascular repair of the tissue.

Response to Arguments to All of the Rejection

Applicants argue that the claims have been amended dot recite specific locations beneath or at the periphery of the ulcer. "It is believed that all claims are clearly distinguishable form the claims

of '587 patent, which does not describe administering the hydrogel matrix by intradermal or subdermal injections beneath or at the periphery of an ulcer."

Applicants arguments have been fully considered but have not been found persuasive.

The US patent claims method for treating vascular disorders, said method comprising administering an effective amount of a matrix to an anatomic site that is in need of increased blood flow, wherein said matrix comprises gelatin and a nitric oxide inhibitor (see claims 17 and 48). While not claimed, the US patent does teach that in order to practice the claimed invention any means may be used to apply or administer the matrix to the desired anatomic site (see col. 5). Thus, in order practice the invention of '587 it would have been obvious to chose any means of administering the matrix to the ulcer, including the modes as claimed. Note that the claims of the US Patent outline that vascularization is desired and the matrix should be administered to any site that is in need of increased blood flow. Thus any mode of administration that achieves that result, including administration in and around the ulcer, is rendered obvious by the patent.

Rejection is maintained.

5. Claims 1-29, 31-42, 46-48, and 50-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6713079 in view of Miller and in further view of Davis or Pickart et al.

The US patent claims a method of promoting wound healing at a site in a mammal by contacting the site with a matrix comprising gelatin, dextran, and one or more of intact collagen, an-L-arginine, L-cysteine, and a divalent chelator (see claim 1). The gelatin is in the form of denatured collagen and is in the concentration range of between .01 to about 40mM of denatured collagen (see claim 2. Note that this concentration range is the same ranged claimed in claim 2 of the instant

application. Further, the concentration of dextran is between 0 to about 2mM (claim 45) and polar amino acid between 3 to about 150 mM (claim 42). Both of the claimed concentration range is with the range claimed in claims 5, 8-9, and 33-36 of the instant application for dextran and the polar amino acids. Moreover, there is also the same concentration ranged claimed for the specific amino acids of glutamic, lysine and Arginine (see claim 8-12 of the US patent and claim 11-15 of the instant application). The nitric oxide inhibitors claimed in the US patent include L-arginine and amino aminoguanidine (see claims 16, 18, 22 of the US patent). These nitric oxide inhibitors, including the concentration claimed in the US Patent, are similar to those claimed in claims 17-24 and 37-44 of the instant application. Note that claim 22 of the US patent claims a composition comprising dextran, denatured collagen, aminoguanidine, glutamic acid, lysine and arginine. This composition is similar to the composition claimed in claim 48 of the instant application. The matrix can be applied to surgical wounds and superficial wound (see claim 23 and 24). The difference between the US Patent and the claimed invention is that the US Patent does not teach the treatment of diabetic foot ulcers and the mode of administration.

However, Miller teach that therapy for the treatment of diabetic foot ulcers includes vascular repair of the ulcers (see abstract). Miller et al. states that an ulcer gores through granulation and reepithelialization (see page 761). Further, the reference suggest that numerous agents can be administered to the to the ulcer site to provide an optimal environment for healing. These include antibiotics and growth factors that result in the stimulation of granulation of tissue (see page 762, paragraph bridging column 1 an d2). It is well known in the art that granulation of tissue consists of new blood vessel formation, fibroblast activity, and re-epitelialization (see col., lines 29-35 of Davis US 5487899 and Col. 1, lines 28-35 of Pickart et al. US 5059588). Mansbridge also teaches that the angiogenesis (i.e. vascularization) is a goal for treating diabetic foot ulcers. This reference disclose

that a goal of treatment for chronic diabetic foot ulcers is to redirect to an acute course and to reinstate normal wound healing. "This requires angiogenesis to improve the blood supply, and provision of suitable substratum for re-reepithelialization." (see page 404). The reference specifically discloses the mechanism of healing diabetic foot ulcers involves multiple components acting in concert, which include angiogenesis and promotion of re-reepithelialization (wound healing) (see page 413). The reference specifically demonstrates the beneficial effects of an angiogenic agent in the treatment of diabetic foot ulcers. The reference specifically points to angiogenesis as one of the mechanism by which this agent exerts the benefit (see page 412-413) Thus, since the US patent teaches method of promoting wound healing and since the art recognizes that revascularatization, a component of angiogenesis, is important in the healing diabetic foot ulcers, it would have been obvious to use the claimed composition for the treatment of foot ulcers because therapy for diabetic foot ulcers include vascular repair of the tissue.

With respect to the mode of administration, while not claimed, the US patent does teach that in order to practice the claimed invention any means may be used to apply or administer the matrix to the desired anatomic site (see col. 5). Thus, in order practice the invention of '587 it would have been obvious to chose any means of administering the matrix to the ulcer, including the modes as claimed. Note that the claims of the US Patent outline that wound healing is desired. Thus any mode of administration that achieves that result, including administration in and around the ulcer, is rendered obvious by the patent.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654